

# RELEASE INSTRUCTIONS (RI)

DOCUMENT NO.:

WHC-CM-5-4

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TO: D. A. Isom Copy #072	H6-08	TITLE: Laboratories Administration RELEASE NO.: 059 DATE PREPARED: May 13, 1997
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## INSTRUCTIONS

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SECTION NO. AND TITLE(S)	REMOVE			INSERT		
	PAGES	REV	DATE	PAGES	REV	DATE
Table of Contents	1 - 6	58	04/30/97	1 - 6	59	05/13/97
Section 1.1, "Safety Priority and Procedure Compliance Policy"	1 - 4	4	12/16/96	1 - 4	5	05/13/97
Section 3.9, "Laboratory Procedures"	all + Appendices	5	01/15/96	all + Appendices	6	05/13/97
Section 3.11, "Format and Content Guide for Analytical Services Technical Procedures"	all + Appendices	0	11/03/95	--	--	--

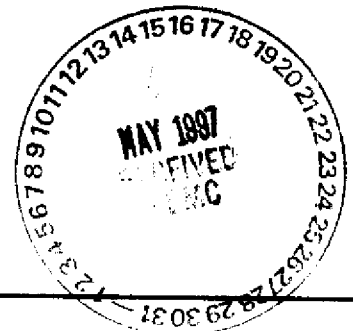
## IMPLEMENTATION NOTICE

(ROUTE A COPY OF THE IMPLEMENTATION NOTICE TO ALL USERS OF THIS COPY OF THE MANUAL)

Section 1.1 updated to reference new LAP-111-000, "Laboratory Procedure Process."

Portions of Section 3.9 moved to new LAP-111-000.

Section 3.11 replaced by LAP-111-000.



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Jean Feaster T6-03

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2.0	ORGANIZATION		
NOTE:	The charter for Analytical Services may be found in WHC-CM-1, <i>Company Policies and Charters</i> .		
2.1	Charters — Section Title (no text)		
2.1.1	222-S Analytical Operations Charter	3	04/13/95
2.1.2	222-S Facility Operations Charter (incorporated into 2.1.1)	Canceled	10/22/93
2.1.3	Program Management and Integration Charter	2	04/05/95
2.1.4	Work Control and Data Management Charter	Canceled	04/26/95
2.1.5	Office of Sample Management	Canceled	04/26/95
2.1.6	Plutonium Finishing Plant Engineering Laboratory	Canceled	07/06/95
2.1.7	Process Laboratories and Technology Charter	Canceled	07/11/95
2.1.8	PUREX Analytical Laboratories Charter	Canceled	07/20/95
2.1.9	Engineering and Technology Services Charter	1	03/31/95
2.2	Committees, Boards, and Task Teams	Canceled	08/17/95
2.2.1	Laboratory Instrument Control Board Charter	Canceled	09/18/96
2.2.2	Chemical Hygiene Committee Charter	1	05/31/95
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3.3	Corrective Action Requirements, Occurrence Categorization, Notification, and Reporting (moved to 6.7)	Canceled	09/13/93
3.4	Data Package Preparation	Canceled	03/03/97
3.5	Administration for Nuclear Materials	4	09/09/96
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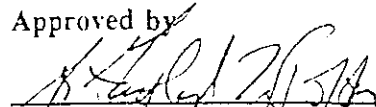
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May 13, 1997

Safety Priority and  
Procedure Compliance Policy

Approved by

  
A. G. King, Manager  
Hanford Analytical Services

Author:  
Organization:

G. B. Griffin  
222-S Operations

## 1.0 PURPOSE

This manual shall be used by all Hanford Analytical Services (HAS) personnel. This includes, for the duration of their assignment, those individuals matrixed or contracted to the organization.

The following policies shall be known and understood by all HAS personnel:

### 1.1 Procedure compliance is mandatory.

Procedures shall be adhered to at all times.

Procedures shall be developed in accordance with this manual (Section 3.9, "Laboratory Procedures") to safely perform work activities that directly affect the operating or design configuration, operability or accuracy of HAS laboratory facilities, systems, equipment or components. Procedures shall be prepared for all anticipated conditions, events, and tasks, in accordance with LAP-111-000, *Laboratory Procedure Process*.

In the event of a situation not covered by an approved procedure, personnel shall be directed to take action so as to:

- Maintain the laboratory in a safe condition
- Minimize personnel injury and radiation exposure
- Minimize radioactive release to the atmosphere
- Protect laboratory equipment.

All HAS procedures are designated as "reference use" as defined in WHC-CM-3-5, *Document Control and Records Management Manual*, Section 12.5, "Technical Procedure Standard." As "reference use" procedures, HAS personnel will not be required to have procedures open and in step-by-step usage if all of the following conditions apply:

- The activity is being conducted by qualified personnel
- The activity is routine and performed frequently
- The activity is of a nature that an error in performance will not have a significant adverse impact on the facility



**Safety Priority and Procedure Compliance Policy**

- A performance copy of the procedure is readily available
- The activity is being conducted exactly as stated in the procedure.

*However*, the procedure will be open and in continuous use if:

- A trainee is performing the activity
- Supervision or management has directed the user to do so
- The activity being conducted is nonroutine, complicated, or infrequent
- There is evidence, in the form of incidents or observations, that show a general weakness in procedural knowledge
- The procedure contains signoffs
- An error in performance could cause significant adverse impact on the facility
- The procedure contains an Operational Safety Limit.

Laboratory personnel shall be capable of performing the immediate action steps of emergency procedures without reference to the procedure.

Activities shall be conducted in a deliberate, methodical manner. In addition to strict adherence to procedures, the individual shall continuously evaluate the activity based on their own logical approach. Before performing any procedure, personnel must think about what could go wrong, what should occur as various steps are performed, and what they should do if expected events do not occur. There are very few problems where the personnel do not have a few moments to plan their actions, consult procedures, and then act.

The requirements for personnel to follow procedures do not relieve them of their responsibility to think and to ensure that their actions maintain the laboratory in a safe condition. If doubt exists in a person's mind about what will happen if they do a certain step of a procedure, the person shall not perform that step. Instead, the person shall stop and notify appropriate management and obtain clarification. Similarly, if a person believes a procedure to be incorrect, that person shall stop and notify management of the discrepancy. The person shall not proceed with the evolution until the procedure is changed and correct in accordance with Section 3.9, "Laboratory Procedures."

**1.2 Safety will be the first priority in all areas of activity.**

**1.3 Safety is a condition of employment.**

**1.4 Personnel will observe all Master Safety Rules.**

Safety Priority and Procedure Compliance Policy

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## 2.0 RECORDS

Any records generated as a result of activities described in this section will be managed in accordance with applicable Records Inventory and Disposition Schedules.

## 3.0 DESIGNATED REVIEWERS

<u>Designated Reviewing Organizations</u>	<u>CMPOC</u>
222-S Operations (Champion)	T6-16
WSCF	S3-28

## 4.0 REFERENCES

LAP-111-000, *Laboratory Procedure Process*, Hanford Analytical Services, Richland, Washington.

WHC-CM-3-5, *Document Control and Records Management Manual*.

WHC-CM-5-4, *Laboratories Administration*.

Safety Priority and Procedure Compliance Policy

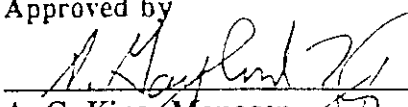
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May 13, 1997

Laboratory Procedures

Approved by

  
A. G. King, Manager  
Hanford Analytical Services

5/8/97

Author:

K. K. Lachut

Organization:

HAS Records

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\*This revision is a total rewrite; therefore, no redlines are used to indicate changes.

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**Laboratory Procedures****1.0 PURPOSE**

This section implements the requirements of WHC-CM-3-5, *Document Control and Records Management Manual*, Section 12.5, "Technical Procedure Standard," as applied to the Hanford Analytical Services (HAS) technical and administrative procedures process. The HAS procedure process is implemented by the Procedures Administration (PA) function of the HAS Records organization. Specific assignment of most process responsibilities, and format and content guidance, are presented in Laboratory Administrative Procedure, LAP-111-000, *Laboratory Procedure Process*.

**2.0 SCOPE**

This section applies to all activities involved in processing the following HAS procedures:

- Laboratory Administrative Procedures (LAPs)
- Laboratory Analytical Procedures (LAs)
- Laboratory Computer Procedures (LCs)
- Laboratory Essential Materials Procedures (LEs)
- Laboratory Operating Procedures (LOs)
- Laboratory Quality Control Procedures (LQs)
- Laboratory Reference Material Procedures (LRs)
- Laboratory Radiological Control Procedures (LRCs)
- Laboratory specific maintenance procedures
- Laboratory specific preventative maintenance procedures
- Laboratory Technology Procedures (LTs)
- Laboratory User Tests (Blue Users)

This section does not apply to desk instructions, other sections of this manual, or to work packages.

For the purposes of this section, the term "procedure" is synonymous with "technical and administrative procedure", unless specifically designated otherwise. See this manual, Section 1.1, for the HAS policy regarding safety priority, and procedure use and compliance.

Deviations from the requirements of this section are documented and approved by waiver as identified in WHC-CM-1-3, *Management Requirements and Procedures*, MRP 2.21, "Controlled Manual Waiver Process."

**2.1 Implementation**

- 2.1.1 Existing procedures are brought into compliance with this process as they are revised.
- 2.1.2 New procedures are developed in compliance with this process.

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**Laboratory Procedures**

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**3.0 DEFINITIONS****Administrative Procedure**

A procedure that dictates a function to be performed to achieve a defined outcome in terms of "what" to do. Procedures may contain such direction as performance steps, best practices, or guidance to perform an activity or controlled process.

**Approval Designator**

The system which establishes approval requirements for a procedure or procedure change based on its importance to Safety, Environment, and Quality. Approval designators are assigned by the procedure's technical authority per the criteria of WHC-CM-3-5, Section 12.7, "Approval of Environmental, Safety, and Quality Affecting Documents," and WHC-CM-7-5, Section 13, "Environmental Issue Identification, Review, and Interface Requirements."

**Controlled Copy**

A hard copy or electronic version of an approved procedure that is maintained at controlled locations (normally in notebooks).

Goldenrod. A performance copy of an approved procedure that is released by PA, placed in controlled locations, and verified to be the most recent revision.

White Copy. A verified copy of a performance procedure or data sheet used for reference purposes or for performance in the field where the use of a performance copy is neither practical or desirable (for example, to avoid contamination or to record one-time performance of an activity). White copies are single-use copies, valid for one-time activity.

**Inactive Procedure**

A procedure that is temporarily not required, pulled from the controlled locations, and placed on "inactive" status in the PA tracking system.

**Lab Procedure Network Directory**

A "read and print only" electronic directory of all current HAS procedures. Procedures designated for specific review are also available.

**Modification**

An alteration to a procedure that does not change the procedure's intent, quality, safety, or process. A modification is referred to as a "field change" for maintenance procedures.

**Periodic Review**

The function of periodically reviewing procedures to verify that they meet and reflect all current applicable technical, administrative, and facility configuration changes that have been made since the last review.

**Procedure Change**

An approved change to a procedure ranging from one word to less than the entire procedure. A procedure change is classified as a revision or modification for a permanent change, or a procedure change authorization for a temporary change.

**Laboratory Procedures****Procedure Change Authorization (PCA)**

The HAS-specific form that authorizes and documents immediate implementation of a temporary change to an existing procedure.

**Procedure Review and Approval Form (PRAF)**

The HAS-specific form that authorizes and documents implementation of a permanent change to an existing procedure or authorizes and documents initiation of a new one.

**Review**

The portion of the procedure process that includes review, verification, validation, and disposition of resulting valid comments.

Validation. The portion of procedure review that tests procedure usability, correctness, and compatibility with the equipment or system.

Verification. The procedure review function that independently evaluates the procedure for technical accuracy.

**Revision**

Any permanent procedure change that alters the results, requirements, or methods by which a procedure is performed, or that does not meet the definition of a modification, including alteration of a regulatory method.

**Technical Authority**

Technical authorities are the cognizant engineers or other facility designated personnel with the necessary training and experience to fulfill the technical responsibilities for the procedures, i.e., maintenance engineers are considered the technical authorities for maintenance procedures.

**Technical Procedure**

A procedure that dictates a function to be performed to achieve a defined outcome in terms of "how" to perform a sequence of actions. Procedures will contain specific procedure steps defining the actions to be taken.

**User Test (Blue User)**

A procedure that has been approved for user testing under the direction of a technical authority.

**Void Procedure**

A procedure that is no longer required by the laboratory, pulled from the field to cancel use, and placed on "void" status in the tracking system.

**Waste Stream Fact Sheet**

Waste Stream Fact Sheets (WSFSs) are prepared in accordance with LAP-106-100, *Waste Stream Fact Sheet Development and Issuance (Predesignation of Waste)*, to record waste stream information.



**Laboratory Procedures****4.0 TRAINING****4.1 Procedure Process Training**

All personnel participating in procedure development, review, approval, and processing are trained and qualified, and have attended the HAS procedure process training. Training requirements, methods, and documentation are established by the Manager, Hanford Analytical Services, and are available in this manual, Section 4.0.

**4.2 Training Requirements**

Training requirements created by a procedure change or development of a new procedure are determined by the technical authority and documented on the PRAF. Training options include full training (or retraining), review of the procedure before performance (read-through), or no training required. These training options must be designated on the PRAF by the technical authority and approved by the approval authority before the procedure can be released.

**5.0 RESPONSIBILITIES****5.1 Manager, Hanford Analytical Services (or designee)**

- Establishes the procedure process defined herein by approval of this manual section
- Issues, on a periodic basis, an approval authority memo that assigns authority and establishes accountability for HAS procedures
- Sets the policy for procedure use and compliance (see this manual, Section 1.1)
- Determines training requirements for procedure writers, technical authorities, and reviewers
- Ensures personnel participating in procedure development, review, and approval are trained and qualified to do so.

Specific responsibilities for all other activities are assigned in LAP-111-000, *Laboratory Procedure Process*.

**Laboratory Procedures****6.0 REQUIREMENTS**

Procedures are developed for anticipated operations, transients, evolutions, surveillances, maintenance, tests, and abnormal or emergency situations. The requirement to develop a procedure or the extent of detail depends on the complexity of the task, the risk associated, the experience and training of the expected user, and the frequency of performance.

**6.1 Documented Basis**

A documented basis is required for all HAS procedures. This basis includes a listing of documents used during procedure development that contains:

- Developmental references (such as vendor material, technical manuals, drawings, etc.)
- Implementing (requirement) references (such as Company Level I and II controlled manuals, Occupational Safety and Health Administration, American National Standards Institute/American Society of Mechanical Engineers, U.S. Department of Energy Orders, national standards, Code of Federal Regulations, Safety Analysis Report, Technical Specifications, etc.).

Requirements identified in the documented basis are integrated into the procedure whenever possible. Those required for actual procedure performance are listed in the procedure "Reference" section.

Other basis documents, such as developmental references, are listed in the procedure "Bibliography" section, and included in the history file, if desired (see Section 7.5.2).

In addition, the documented basis for each procedure change or new procedure is recorded on the PRAF. The "Basis for Procedure Change/New Procedure" block includes the reason for the change or provides justification for a new procedure. This basis is vital in documenting the evolution of each procedure. As part of the PRAF, it becomes a permanent part of the history file.

**6.2 Procedure Identification**

Laboratory procedures are assigned a unique identification number by the technical authority and/or PA (in accordance with LAP-111-000, Appendix A). This number appears on the bottom of each page of the procedure. All procedures also carry a revision/modification identifier that appears on the bottom of each page. Excepting maintenance procedures, revisions are classified by the first character, a letter, and modifications are identified by the second character, a number. Revision/modification identifiers are separated by a hyphen (for example, A-0).

**Laboratory Procedures****6.3 Use of Controlled Copy Procedures**

Approved procedures are readily available in controlled locations throughout HAS facilities. Normally, they are maintained in notebooks or electronically, via the Laboratory Procedure network directory. Normally, only PA personnel are authorized to make changes to goldenrod procedures in these controlled locations; however, exceptions do exist and are documented.

Goldenrod procedures are controlled performance copies. They are identified as valid by a triangular release stamp and notebook number on page 1, and by being issued on goldenrod paper. They are kept current by inserting PCAs or by issuing updated copies.

Goldenrods are normally the only valid performance copies used to perform an activity; however, use of verified white copy procedures is permitted; for example, when a goldenrod is neither practical or desirable:

- To avoid contamination
- To perform a procedure requiring signatures, such as for hold points, etc.

White copies are single-use copies, valid for a one-time activity. White copies must be verified *before use* to be the most recent revision and documented as such by:

1. Comparing the procedure page-by-page with the same goldenrod in the laboratory
2. Contacting PA to verify the procedure is indeed the latest revision before use, *then*
3. Printing and signing the user name and date in the "approved for use" block in the lower right-hand corner with user name and date.

Upon completion of the activity, the white copy is destroyed or included as part of the work package, surveillance, shift log or activity for which it was used.

White copies are obtained electronically on the Lab Procedure network directory or in hard copy from PA.

**6.4 User Test ("Blue User")**

A user test is a procedure normally written for one-of-a-kind, nonrepetitive activities. In addition, it may be performed to document a peer review and to qualify a method. It can also evaluate a new or changing procedure under controlled conditions.

User tests are accompanied by a PRAF and all appropriate approval signatures required for any procedure release. User tests are printed on blue paper for unique identification.

The user test is controlled by the TA. Changes during performance are handled as modifications or revisions, depending on their impact to the actual test. Modifications of approval designator "NA" are documented by marking up, initialing, and dating the hard copy. These changes

**Laboratory Procedures**

are also noted in the shift log, and approved by the TA and approval authority or the Shift Manager or designee. All other changes (including revisions) are handled via the PCA process described herein.

Any active procedure being converted to a blue user is inactivated during the blue user test period.

**7.0 PROCEDURE CHANGE CONTROL, REVIEW, AND APPROVAL****7.1 Procedure Review and Approval Form (PRAF)**

The PRAF form authorizes and documents the processing of permanent procedure changes or approvals of a new procedure. It acts as the authorization for procedure development or changes. It documents basis for changes and justification for new procedures, reviews and approvals, and disposition of comments. The PRAF becomes a permanent part of the procedure history file. All procedure approvals are obtained and documented on the PRAF.

The requestor of procedure changes or new procedures provides information in the shaded areas of the PRAF to PA to initiate and implement the change process. The most current PRAF is available from PA or electronically on the Lab Procedure network directory. See Attachments 2 and 3.

**7.2 Change Control**

Procedure changes are necessary to ensure procedures reflect current practices, equipment changes, and new requirements. When need for a change to an approved procedure is identified, the change is initiated and processed in accordance with this section. The review and approval process for each procedure change is documented on a PRAF.

Changes to laboratory technical procedures are considered either modifications or revisions.

**7.2.1 Modifications (or Field Changes)**

Modifications are approved on a PRAF and in accordance with this section.

Modifications are limited to:

- Alterations that do not change the procedure's intent, quality, safety, or process
- Format changes that do NOT alter the technical content of the procedure
- Correction of grammatical, typographical, or spelling errors that do NOT affect:
  - numbers (other than page, step, table, figure title numbers, or obvious typographical errors)

**Laboratory Procedures**

- units of measure, including updates to metric configuration
- nameplate information/data
- acceptance QC criteria, detection limit, accuracy, and precision
- Update of position or organizational names or titles, if the change does not alter responsibilities with regard to HAS laboratory procedure functions
- Update of references, unless there has been a change in the reference that affects the technical content of the procedure
- Pagination, table, or figure title number changes.

**7.2.2 Revisions**

Revisions include any change that does not meet the criteria of a modification, including modification of a regulatory method. Typical revisions include changing the technical content of a procedure, altering results, or affecting the approval designation. A technical change is also initiated when a procedure is determined to be difficult to follow. Normally, no more than five modifications are incorporated before a procedure revision is required; however, exceptions do exist, based on extent of changes and procedure flow. A technical change to a procedure is approved on a PRAF. Technical changes made and incorporated into the procedure conform to criteria set forth in this section.

**7.2.3 Incorporation of Changes**

Approved changes are incorporated in accordance with this section. Pen and ink changes are not allowed on performance copies. The use of tape or obliterating agents in a procedure is also not allowed. A procedure revision is initiated when a procedure has been affected by changes to the point the procedure is difficult to follow.

**7.2.4 Temporary Changes (PCAs)**

Temporary changes are issued via Procedure Change Authorization (PCA) to immediately implement a temporary change or permit a temporary departure from an existing procedure for a 90-day period of time or for the duration of an event. Extensions up to 30 days may be obtained by contacting PA, who extend the expiration date and issue new copies. PCAs are issued on pink paper and considered controlled documents. The most current PCA form is available from PA or on the Lab Procedures network directory. See Attachment 1.

Only one PCA is allowed on any one procedure at any given time. Any outstanding PCA that exists against a procedure is incorporated into the new revision or canceled upon issuance of a new revision. A new PCA is issued if needed.

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Procedure Change Authorizations are required to be reviewed and approved per the approval designator assigned by the TA (refer to WHC-CM-3-5, Section 12.7, Table 1). The following also apply:

- The requestor (normally technical authority) submits an approved PCA to PA at the time of the change.
- A PCA number (for example, SL-XXXXX) is assigned by PA.
- The PCA number is placed on each page of the procedure that is changed by the PCA, and on each PCA continuation page.
- PCA format can be any of the following:
  - PCA continuation pages. A new PCA continuation page is used for each page of the procedure that is changed. Changes on multiple pages of a procedure cannot be combined onto one PCA continuation sheet.
  - Annotated pages. If PCA changes allow, a marked-up copy of procedure pages are attached to the PCA. If this method is used, each changed page shall be identified on page 1 of the PCA.
  - Annotated document. A marked up copy of the entire procedure is attached to the PCA.

If a deviation from a procedure is required and a PCA number cannot be obtained from PA in a reasonable period of time (such as during a weekend), a mark-up copy of the procedure is made and documented on a PCA form, approved in accordance with the approval designator, and submitted to PA on the next business day for processing.

If a PCA is written that applies only for a specific time period or for specific activities, that PCA may be canceled upon completion of the work activity or time period. Cancellation of a PCA is accomplished by obtaining the original copy of the PCA from PA and acquiring the required dated approvals in the "Work Completion/Cancellation" block.

**Laboratory Procedures****7.2.5 Inactivations and Voids**

When procedures are temporarily or no longer required, they are removed from active status. The following are used to remove an active procedure to an inactive (hold) or void (canceled) status.

1. Technical authorities and/or approval authorities notify PA that a procedure needs to be removed from active status. The notification to be inactivated or voided, and the effective date for change of status is included. Normally, a PRAF is used for this notification.
2. Procedures Administration enters the inactive or void notification into the tracking system, removes the procedure from the controlled location(s), stamps the original procedure "Inactive" or "Void," and files the notification in the procedure history file in the Laboratory Technical Information Center (LTIC).

**7.2.6 Reactivations**

Reactivation of an inactive procedure is initiated and documented on a PRAF. Normally, reactivations result from a renewed need for a procedure or to restore a procedure that has passed its periodic review. An inactive document can be reactivated and placed back into use without a review if the periodic review date has not passed. However, if the periodic review date has passed, the procedure requires a full review by the technical authority, approval authority, and those required by the approval designator before reissue. Void procedures cannot be reactivated.

**7.3 Review**

All organizations and personnel that formally request or are required to review a procedure are provided an opportunity for such review. Each reviewer documents comments in black ink and signs the PRAF after comment resolution and incorporation is complete. In such instances when one reviewer marks up a change after others have signed for their review, the procedure and/or change will be rereviewed and new signatures obtained as determined by the TA. Comments received during such reviews are facilitated by PA, and resolved in total between the technical authority and the reviewers. Normal review time is five working days. Deviations in review periods are negotiated between the technical authority and reviewer, and PA is notified.

Minimum review and approval requirements for new or revised procedures, modifications, and PCAs include the technical authority, approval authority, those required by the approval designator, and PA.

The approval designator of the PRAF indicates the impact of the change being approved, not that of the original procedure (unless the procedure is new). The approval designator of the procedure and the PRAF are not always the same.

Cross-disciplinary reviews are performed whenever any of the following conditions apply.

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- The response of a system under the direct control of another group is altered and notification of the affected group is required.
- The steps in a procedure may affect the use or operation of equipment under the control of another group.
- Cases where expertise in specific disciplines or specialized training are needed beyond that of the primary reviewer(s) to ensure a complete technical review of the procedure.

Requests for cross-disciplinary reviews may be documented on page 2 of the PRAF and review signatures captured on page 1 in the "Procedure Review" section.

**7.3.1 Verification**

Procedure verification is performed by the technical authority on new and revised procedures and documented by signature on the PRAF. Verification also includes additional reviews requested by the technical authority by any other organizations, personnel, or disciplines to ensure the procedure is free of technical errors.

- Verify information contained within the procedure is accurate and complete
- Verify the procedure is free of errors, easy to understand, and meets the guidelines for content and format
- Verify applicable safety requirements or limits are identified and satisfied. The reviewer checks for omissions of Technical Specification or Operational Safety Requirements provisions that may not be identified in the procedure.
- Verify the procedure does not contain steps that could potentially lead to Technical Specification or Operational Safety Requirements violations, expose personnel or the environment to hazardous conditions, or cause equipment damage.
- Verify the procedure can be accomplished in the sequence written.
- Verify the procedure provides for easy interaction between groups, and efficient use of resources.
- Verify references specified in the procedure are applicable to the procedure being performed.

**7.3.2 Validation**

Procedure validation is performed on all new procedures and procedure revisions, excepting LAPs, by one of the methods described below. It is not required for procedure modifications. The validation method is determined by the technical authority based on the scope, hazard risk, and application of each procedure. Validation is normally performed by personnel who use the procedure.



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**Laboratory Procedures**

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Validation is documented by signature on the PRAF and retained in the procedure history file. The validation steps contained in the checklist in Attachment 4 are addressed or the checklist itself may be used and included in the history file.

The "walk-through" method is preferred for validation. Alternate methods may be used when a walk-through is not practical. The following explain the walkthrough method and some alternate methods.

- Walk-through method. A method in which the intended users take the procedure to the location where the task is to be done and, without actually performing the task, ensure that each step is correct and readily usable as written. Where available, a simulator may be used for this method.
- Reference method. A method where an analytical review that does not simulate actual operation, but validates the procedure through document reviews. This method may be used for procedures developed from a previously performed procedure (such as a work package, test procedure or vendor technical manual). To use this method, the procedure must have been performed using the parent document and must contain the same instructions.

The procedure is then validated based on the fact that the instructions were performed successfully via another document.

- Simulation Method. A method whereby personnel who would normally perform the procedure do so on simulators or mock-ups of the equipment.
- Table Top Method. A method whereby personnel explain and/or discuss procedure action steps. Appropriate drawings and references are used.

### 7.3.3 Periodic Review

To ensure the technical accuracy and adequacy of procedures, the following review cycle has been established for HAS procedures, based on the associated approval designator:

- Any Safety (S) approval designator — 2 years
- Any Environmental (E) or Quality (Q) approval designator — 3 years
- Any Not Applicable (NA) approval designator — 5 years.

This review cycle meets the requirements of WHC-SP-0708, *Westinghouse Hanford Company Conduct of Operations Manual*, Chapter 16, "Operations Procedures" and WHC-CM-3-5, Section 12.5. Periodic reviews are based on the time interval from initial release of the procedure, with the cycle reset for any completed revision. The new date of periodic review is established from the date of release.

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Procedures are tracked by PA to determine when periodic reviews are required. Technical authorities are notified to ensure periodic review and any required changes are completed as scheduled. The review is documented on the PRAF and submitted to PA for processing.

Any procedure that has not been reviewed, and/or had changes completed, and been released by its required periodic review date is considered invalid for use. It will be inactivated on the day following the periodic review due date. These procedures will be removed from controlled locations and remain in inactive status until review is completed or notice of reactivation is processed.

**7.3.4 Final Administrative Review**

Before release for use, a final administrative review is performed by PA to ensure the procedure is accurate and consistent with the procedure process defined herein. The following are addressed in the final review.

- The procedure meets guidance for format and content.
- References specified in the procedure are current and applicable.
- Reviews are performed by all identified reviewers.
- Any change made after initial reviewer signature has been rereviewed and approved (as determined by the TA).
- Comments are dispositioned and incorporated, as applicable.

**7.4 Approval and Telecon Approval**

A procedure is approved, at a minimum, by the TA, approval authority, and PA in accordance with the assigned approval designator. Procedure approval is obtained on the PRAF and can be in written form with signature or initials, by documented telephone conversation (telecon), or sent electronically via cc:Mail or telefax. Signatures are required in black ink only.

- The person called to perform the review and grant an approval accepts full responsibility for ensuring that the review performed is adequate for the approval granted.
- The person requesting approval documents the approval on the PRAF or procedure by printing the date and the name of the person called near the change made and approved; then signs and prints their name near the name of the person giving approval and indicates the approval was "per telecon."

**Laboratory Procedures****7.5 Records**

Procedure Review and Approval Forms and associated procedure process documentation become quality records. Use care to ensure readability and comprehension. Use black ink only.

**7.5.1 Indexes and Files**

The following indexes and files are maintained by PA. Most hard-copy and history files are maintained in the LTIC.

- A master database of procedures
- A master file containing a controlled master of the most current version of the procedure generating goldenrods.
- The back-up electronic (computer based) procedure master file
- Emergency operating procedures are maintained in both hard-copy and electronic format.

**7.5.2 History File**

A history file is established and maintained for each procedure. It contains a record of procedure reviews, approvals, and comments and their disposition. It may also include basis documents such as developmental references as provided by the TA. The file is available in hard-copy or via other archival media.

**7.5.3 Disposition**

Any records generated as a result of employing HAS procedures will be processed through data package, work control, or other laboratory activities and dispositioned in accordance with applicable sections of WHC-CM-3-5, *Document Control and Records Management Manual*, and applicable Records Inventory and Disposition Schedules.

**8.0 DESIGNATED REVIEWERS**

<u>Designated Reviewing Organizations</u>	<u>MSIN</u>
Procedures Administration (Champion)	T6-03
222-S Procedures Conduct of Operations Champion	T6-20
Quality Systems	T6-16
Operations Support	T6-51
WSCF	S3-28
222-S Operations	T6-12

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9.0 REFERENCES

LAP-106-100, *Waste Stream Fact Sheet Development and Issuance (Predesignation of Waste)*, Hanford Analytical Services, Richland, Washington.

LAP-111-000, *Laboratory Procedure Process*, Hanford Analytical Services, Richland, Washington.

WHC-CM-3-5, *Document Control and Records Management Manual*.

WHC-CM-7-5, *Environmental Compliance Manual*.

WHC-SP-0708, *Westinghouse Hanford Company Conduct of Operations Manual*.

Laboratory Procedures

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ATTACHMENT 1

HANFORD ANALYTICAL SERVICES  
PROCEDURE CHANGE AUTHORIZATION

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Attachment 1-3 of 4

## Laboratory Procedures

<b>Analytical Services</b> <b>Procedure Change Authorization</b>		<b>Approval Designator</b>  	<b>PCA No.</b>  	<b>Page 1 of</b> _____
<b>Procedure No.</b>  		<b>Rev/Mod</b>  	<b>PCA Effective Date</b>  	
<b>Title</b>  		<b>PCA Expiration Date</b>  		
<b>Facility</b> <input type="checkbox"/> 222-B <input type="checkbox"/> WSCF		<b>PCA Type</b> <input type="checkbox"/> Temporary <input type="checkbox"/> Contribution Sheet Attached <input type="checkbox"/> Extension <input type="checkbox"/> Annotated Pages Attached <input type="checkbox"/> Annotated Document Attached		
<b>Change Requested By</b>  		<b>Guided/Used Locations (Performance Copies):</b>  		
<b>(Name)</b>  		 		
<b>(New Organization)</b>  		<b>(Phone)</b>  		
<b>Approval</b>  		<b>Reason for Change</b>  		
<b>(Technical Authority)</b>  		 		
<b>(Operations)</b>  		 		
<b>(Safety)</b>  		 		
<b>(Environmental)</b>  		 		
<b>(QA)</b>  		 		
<b>(Other)</b>  		 		
<b>(Other)</b>  		 		
<b>Final Approval</b>  		<b>Work Completion/Cancellation</b>  		
 		<b>Due to</b> <input type="checkbox"/> Work Completed (prior to expiration) <input type="checkbox"/> Other — Explain:		
<b>(Approval Authority)</b>  		 		
<b>Distribution:</b>  		<b>SIGNATURES</b>  		
<b>Technical Authority</b> _____		<b>Technical Authority</b> _____		
<b>Approval Authority</b> _____		<b>Date</b> _____		
<b>LTS Support</b> <u>K. M. Higley T6-51</u>		 		
<b>Other</b> _____		<b>Approval Authority</b> _____		
<b>Other</b> _____		<b>Date</b> _____		

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Attachment 1-4 of 4

Attachment 1. Hanford Analytical Services  
Procedure Change Authorization (Sheet 2 of 2)

Analytical Services Procedure Change Authorization Continuation Sheet	Approval Designator	PCA No. SL-	Page ____ of ____
Description of operator actions required to make equipment and procedures compatible, if applicable.			
Description of Change (Page/Step no./Changes)			



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ATTACHMENT 2

PROCEDURE REVIEW AND APPROVAL FORM

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## Laboratory Procedures

ANALYTICAL SERVICES					
Procedure Review and Approval Form				Page	of
<b>Procedure Number</b>	<b>Current Rev./Mod.</b>	<b>Approval Designator for Change</b>	<b>Technical Authority / Approval Authority</b>		
<b>Title</b>			<b>Change Requested By</b>		
			<b>Signature/Date</b>		
			<b>Org.</b>		
<b>Keywords (3)</b>			<b>Old/new Locations (performance copies)</b>		
[ ] New Procedure — Validation signature required below	Rev./Mod.	Rev./Mod.	[ ] PERIODIC REVIEW OF LABORATORY PROCEDURE		
[ ] Revision — Validation signature required below		to	Procedure Review Date		
[ ] Modification — No validation required		to	Date Due to Procedures Administration		
[ ] PCA No. incorporated			<input type="checkbox"/> This laboratory procedure has been reviewed as required and found to be satisfactory for continued safe operation.  <input type="checkbox"/> Change Required		
[ ] User Test ("Blue-User") [ ] User Test 30-day Extension			(Technical Authority) _____ (Date) _____		
[ ] Inactivate [ ] Void [ ] Reauthorize			(Approval Authority) _____ (Date) _____		
<b>Training Required:</b> [ ] Training/Retraining [ ] Review before performing [ ] None required			<b>Basis for Procedure Change/New Procedure:</b>		
			Implementing this change will require operator actions to make lab equipment/systems and procedures compatible?		
			[ ] Yes (see page 2) [ ] No		
<b>Procedure Review</b> (please sign in black ink only)					
As Is	With Add'l Changes (see page 2)	NOT ACCEPTABLE (see page 2)	(Technical Authority Signature)	(Print Name)	(Date)
[ ]	[ ]	[ ]	(Validator Signature)	[ ] walk-through [ ] reference [ ] simulation [ ] table-top	(Date)
[ ]	[ ]	[ ]	(Operations Signature)	(Print Name)	(Date)
[ ]	[ ]	[ ]	(Safety Signature)	(Print Name)	(Date)
[ ]	[ ]	[ ]	(Environmental Signature)	(Print Name)	(Date)
[ ]	[ ]	[ ]	(QA Signature)	(Print Name)	(Date)
[ ]	[ ]	[ ]	(Other Signature)	(Org.) (Print Name)	(Date)
[ ]	[ ]	[ ]	(Other Signature)	(Org.) (Print Name)	(Date)
[ ]	[ ]	[ ]	(Other Signature)	(Org.) (Print Name)	(Date)

## Laboratory Procedures

## Attachment 2. Procedure Review and Approval Form (Sheet 2 of 2)

Procedure Number / Current Rev/Mod	Page	of
Description of operator actions required to make equipment and procedures compatible, if applicable.		
Review and Comment		
Signature _____ Title/Org _____ Date _____		
Review and Comment		
Signature _____ Title/Org _____ Date _____		
APPROVAL AUTHORITY		
<input type="checkbox"/> ALL OBJECTIONS RESOLVED <input type="checkbox"/> UNRESOLVED ISSUE EXISTS		
Signature _____ Date _____		
For Procedures Administration Use Only		
PROCEDURES ADMINISTRATION (review for WHC-CM-5-4 compliance, insert release date, move to network, distribute, file master) Distribution Intiple _____		
Signature _____ Date _____		

ATTACHMENT 3

MAINTENANCE PROCEDURE REVIEW AND APPROVAL FORM

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## Laboratory Procedures

## Attachment 3. Maintenance Procedure Review and Approval Form (Sheet 1 of 2)

ANALYTICAL SERVICES Maintenance Procedure Review and Approval Form				Page ____ of ____
Procedure Number _____	Current Rev./Chg _____	Approval Designator for Change _____	Manager/Approval Authority _____	
Title _____			Technical Authority _____	
Keywords (3): _____			Org. <u>LAB ENGINEERING</u>	
			Validator (if applicable) _____	
			Maintenance Engineer _____	
<input type="checkbox"/> New Procedure <input type="checkbox"/> Revision — Validation signature required below <input type="checkbox"/> Field Change — No Validation required <input type="checkbox"/> Inactivate <input type="checkbox"/> Void <input type="checkbox"/> Reauthorize			<input type="checkbox"/> PERIODIC REVIEW OF LABORATORY PROCEDURE Procedure Review Date _____ Date Due to Procedure Administration _____ <input type="checkbox"/> This laboratory procedure has been reviewed as required and found to be satisfactory for continued safe operation. <input type="checkbox"/> Change Required	
			(Technical Authority) _____ (Date) _____ (Manager/Approval Authority) _____ (Date) _____	
Basis for Procedure Change/New Procedure: _____ (Requested By/Date) _____ (Org) _____			TS/OSR Related? <input type="checkbox"/> No <input type="checkbox"/> Yes Ref: _____ Does revision require CERS or JCS Data Sheet (s) revision? <input type="checkbox"/> Yes <input type="checkbox"/> No	
			RECALL INFORMATION: <input type="checkbox"/> NEW PROCEDURE <input type="checkbox"/> FREQ. CHANGE <input type="checkbox"/> N/A Performance Frequency: _____ Start (after procedure issue): _____	
<b>Procedure Review</b> (please print name and sign in black ink only)				
<b>ACCEPTABLE</b> As Is With Add'l Changes		<b>NOT ACCEPTABLE</b> (see reverse)		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(Technical Authority) _____ (Date) _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(Validator) <input type="checkbox"/> walk-through <input type="checkbox"/> reference <input type="checkbox"/> simulation <input type="checkbox"/> table-top (Date) _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(Operations) _____ (Date) _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(Safety) _____ (Date) _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(Environmental) _____ (Date) _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(QA) _____ (Date) _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(Other) _____ (Org.) _____ (Date) _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(Other) _____ (Org.) _____ (Date) _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(Other) _____ (Org.) _____ (Date) _____	

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## Attachment 3-4 of 4

## Attachment 3. Maintenance Procedure Review and Approval Form (Sheet 2 of 2)

<b>Review and Comment</b>			
Signature _____	Tbl/Org _____	Date _____	
<b>Review and Comment</b>			

**APPROVAL AUTHORITY**

Signature _____	Tbl/Org _____	Date _____
-----------------	---------------	------------

[ ] ALL OBJECTIONS RESOLVED  
[ ] UNRESOLVED ISSUE EXISTS

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**For Procedures Administration Use Only**

Signature _____	Date _____
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**PROCEDURES ADMINISTRATION Review for WHIC-CH-5-d compliance; insert release date, move to network, notify work control, file masterj Dirct, include \_\_\_\_\_**

Signatures _____	Date _____
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ATTACHMENT 4  
VALIDATION CHECKLIST

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## Laboratory Procedures

This checklist is designed to assist personnel in performing a procedure review. Validation methods are defined in paragraph 6.1.2. Technical comments, if any, are recorded on a PRAF or on the back of this checklist, if it is used.

Review Performed	Validation Method
Verification <input type="checkbox"/> Validation <input type="checkbox"/>	Walk Thru <input type="checkbox"/> Reference <input type="checkbox"/> Simulation <input type="checkbox"/> Table Top <input type="checkbox"/>

1. Can the procedure be performed in the sequence written? ☐ Yes ☐ No ☐ N/A
2. Can the individual steps be performed? ☐ Yes ☐ No ☐ N/A
  - Each step specifically identified the action to be taken (such as open, shut, turn) ☐ Yes ☐ No ☐ N/A
  - Limitations are expressed quantitatively ☐ Yes ☐ No ☐ N/A
  - Equipment and parts are identified clearly and reflect exact equipment nomenclature ☐ Yes ☐ No ☐ N/A
  - Steps requiring sign-off are clearly delineated and adequate sign-off space provided ☐ Yes ☐ No ☐ N/A
  - The procedure accurately reflects the current configuration of the process or equipment ☐ Yes ☐ No ☐ N/A
  - The amount and level of information is adequate ☐ Yes ☐ No ☐ N/A
3. Can the user locate and identify all equipment referred to in the procedure? ☐ Yes ☐ No ☐ N/A
4. Does the procedure provide actions or procedures which must be completed prior to performance (Prerequisites)? ☐ Yes ☐ No ☐ N/A
  - Plant, system, or equipment lineups? ☐ Yes ☐ No ☐ N/A
  - Precautions to be observed? ☐ Yes ☐ No ☐ N/A
  - Plant, system, or equipment limitations? ☐ Yes ☐ No ☐ N/A
  - By part number or other unique nomenclature? ☐ Yes ☐ No ☐ N/A
5. Can the user perform the procedure without obtaining additional information from persons or documents? ☐ Yes ☐ No ☐ N/A
  - If other documents are needed, are they referenced clearly enough to allow the operator to proceed efficiently? ☐ Yes ☐ No ☐ N/A
6. Does the procedure include adequate QA, Safety, Environmental, or HPT hold points? ☐ Yes ☐ No ☐ N/A
7. Are instructions written in short, concise, identifiable steps as opposed to multi-step paragraphs? ☐ Yes ☐ No ☐ N/A
  - In the correct order to perform the task? ☐ Yes ☐ No ☐ N/A
  - Missing? ☐ Yes ☐ No ☐ N/A

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- Detailed enough to allow performance without interpretation? ☐ Yes ☐ No ☐ N/A
- Too detailed? ☐ Yes ☐ No ☐ N/A
- 8. Are notes, cautions, or warnings placed directly ahead of the steps to which they apply? ☐ Yes ☐ No ☐ N/A
- 9. Does procedure include signoff spaces for independent verifications? ☐ Yes ☐ No ☐ N/A
- 10. Are graphs, charts, and tables adequate for readability and use?
  - Are they compatible with the procedure? ☐ Yes ☐ No ☐ N/A
  - Can values be extracted or interpolated easily? ☐ Yes ☐ No ☐ N/A
  - Are units of scale and measurement useable? ☐ Yes ☐ No ☐ N/A
  - Are titles descriptive of contents and use? ☐ Yes ☐ No ☐ N/A
- 11. Do included worksheets or data sheets provide sufficient space to record data or perform necessary calculations? ☐ Yes ☐ No ☐ N/A
- 12. If any follow-up action, test, or procedure must be performed, is that action clearly identified?
  - Are correct personnel specified? ☐ Yes ☐ No ☐ N/A
  - Are reporting chains specified correctly? ☐ Yes ☐ No ☐ N/A
  - Are actions or referenced procedures specified correctly? ☐ Yes ☐ No ☐ N/A
- 13. Is the procedure updated to current guidelines?
  - Technical guidelines (such as Tech Specs) ☐ Yes ☐ No ☐ N/A
  - Format editorial requirements ☐ Yes ☐ No ☐ N/A

Reviewed By:

\_\_\_\_\_  
Print Name\_\_\_\_\_  
Signature\_\_\_\_\_  
Date